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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/089,871	06/04/1998	RUDOLF CAROLUS MARIA BARENDSE	97253-A	3289

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

33

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/089,871

Applicant(s)

BARENDSE ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-28,31-35,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-28, 31-35, 39-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Status of the Application***

Claims 18-28, 31-35, 39-40 are pending.

Applicant's amendment of claim 31 in Paper No. 32, filed on 8/11/2003 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Claim Rejections - 35 USC § 112, Second Paragraph***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18-28, 31-32, 34-35 and 39-40 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. This rejection was applied due to the recitation of "of "non-fibrous solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer" for the reasons discussed at length in Paper No. 30, mailed on 2/24/2003.

4. Applicants argue that claims 18-19 do not recite "digestible" or "non-digestible", therefore these terms should not be read into the claims. Furthermore, Applicants submit that if a carrier is 100% starch, then it fulfills the requirement of comprising at least 15% starch and that the specification provides for embodiments in which the edible carbohydrate polymer content of the solid carrier varies from 15% to 100 (w/w).

5. In view of Applicant's assertion that the terms "digestible" or "non-digestible" should not be read into the claims, it is assumed from Applicant's response that the intended meaning of the term "non-fibrous solid carrier" encompasses any edible solid material lacking a filamentous structure which may or may not be digestible. As such, this rejection is hereby withdrawn.

***Claim Rejections - 35 USC § 102***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 31-33 were rejected under 35 U.S.C. 102(b) as being anticipated by Nielsen et al. (WO 95/28850, November 2, 1995; cited in previous Office Actions).

8. Amended claim 31 now recites a composition comprising a phytase-containing granulate prepared by providing a non-fibrous solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer and a solution having a concentration of at least 14000 FTU per gram of solution. In view of the fact that Nielsen et al. does not teach such composition, this rejection is hereby withdrawn.

***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 18-21, 24-28, and 31-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995; cited in previous Office Actions) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996).

11. Claims 22-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995; cited in previous Office Actions) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) as applied to claims 18-21, 24-28, and 31-35 above, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978; cited in previous Office Actions).

12. Claims 39 and 40 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995; cited in previous Office Actions) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) and Markussen et al. (U.S. Patent No. 4106991, 1978; cited in previous

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Office Actions) as applied to claims 22-23 above, and further in view of Haarasilta (GB 2-139868A, 1984).

13. These rejections have been discussed at length in Paper No. 30, mailed on 2/24/2003.

14. Applicants argue that Applicants discovered culture conditions and filtration steps with resulted in an aqueous solution having a phytase concentration of 14000 FTU/gram of aqueous liquid or greater. According to Applicants, granulates with more concentrated phytase activity were found much more stable than granulates with less concentrated phytase activity and that making granules using a high activity phytase liquid resulted in increased pelleting stability compared to granules made with lower phytase activity liquid as shown in Example 5. Applicants also argue that Nielsen et al. states ranges of phytase activity for the animal feed additive although does not mention whether these ranges apply to a granulate or liquid enzyme product. Applicants submit that Nielsen does not demonstrate any granulate or liquid preparations with the high phytase activity concentrations as presently claimed. In addition, Applicants submit that in the working examples of Nielsen et al., Phytase Novo<sup>TM</sup> from Novo Nordisk ranging in activity from 5000-7370 FYT is the source of phytase and that Phytase Novo<sup>TM</sup> is available as a coated granulate product at 2500 FYT/g and as liquid at 5000 FYT/g. Applicants submit the Data Sheets for Phytase Novo<sup>TM</sup>. According to Applicants, while not specifically stated, Nielsen most likely used the liquid product, therefore Nielsen does not describe a phytase-containing granulate composition with a phytase activity of at least 6000 FTU/gram or a liquid composition comprising at least 14000 FTU/gram of liquid. In regard to Ghani, it is Applicant's position that neither of these references teach the claimed invention or describe the importance of creating compositions with high phytase activity. In regard to Markussen, it is Applicant's position that this reference does not supply what is missing from Nielsen et al. and Ghani. In regard to Haarasilta, Applicants submit that this reference does not supply what is missing from Nielsen et al., Ghani or Markussen. It is Applicant's conclusion that the cited references do not support a prima facie case of obviousness.

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15. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejections previously applied. The Examiner acknowledges the specification's teachings in regard to a more concentrated liquid formulation containing at least 14000 FTU/g solution and the results shown in Table 2 (Example 5). It is noted however that according to Table 2 and what is described in Example 5, it is not apparent that making granules using a high activity phytase liquid resulted in increased pelleting stability compared to granules made with lower phytase activity liquid. Table 2 describes 3 different granulates comprising increasing amounts of phytase per gram and increasing enzyme yield after pelleting. While not explicitly described, it is assumed that % enzyme yield refers to how much enzyme activity is left after exposure of the granules to heat. Each of the granulates tested was made with different liquid compositions of the phytase. Table 2 does not show any results with granules having the same phytase concentration but made with liquid phytase solutions of different concentration. Therefore, while one of skill in the art can believe that increasing phytase concentration in the granules may result in increase pelleting stability, one cannot reasonably conclude that granules having the same phytase concentration but made of liquid phytase solutions having different phytase concentrations would have different pelleting stability, as asserted by Applicants. As such, the limitation in regard to the phytase concentration in the liquid solution used to make the granules is not sufficient to reasonably conclude that a phytase granulate containing at least 6000 FTU/g made with such solution is any different from another phytase granulate containing the same phytase in the same concentration.

While the Examiner acknowledges that Nielsen et al. does not teach a liquid phytase solution of 14000 FTU/g liquid, the Examiner disagrees with Applicant's contention that the instant reference does not teach a phytase granulate of at least 6000 FTU/g. As indicated in page 10, lines 16-21 of Nielsen et al., the animal feed additive is a granulate enzyme product. As acknowledged by Applicants, Nielsen et al. describes that the animal feed additive can have 500-10000 FTY/g. As such, Nielsen et al. teaches an animal feed additive which is a granulate having at least 6000 FTU/g. While one could argue that the

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instant granulate was not described in the working examples of Nielsen et al., the teachings of Nielsen et al. clearly describe a granulate having at least 6000 FTU/g as indicated above. In regard to the working examples provided by Nielsen et al., it is noted that while it is agreed that the phytase used in the examples appears to be Phytase Novo<sup>TM</sup>, the Examiner disagrees with Applicant's contention that the Phytase Novo<sup>TM</sup> used by Nielsen et al. in all the examples provided is in liquid form or that its concentration is 5000 FYT/g as shown in the Data Sheet provided as Appendix A by Applicants.

According to Example 1 of Nielsen et al., the Phytase Novo<sup>TM</sup> used is 6900 FYT/g (page 14, line 1). In addition, in page 17, line 7 of Nielsen et al., a Phytase Novo<sup>TM</sup> having 7370 FYT/g was used.

Furthermore, there is no teaching or suggestion in the disclosure of Nielsen et al. which would lead one of skill in the art to reasonably conclude that the phytase formulation used is in liquid or solid form. While it is agreed that the mixture containing the soy meal or the soy protein concentrate and the phytase contains some moisture, there is no indication that the Phytase Novo<sup>TM</sup> used was in liquid form.

Therefore, for the reasons set forth above and those of record, the teachings of Nielsen et al. in view of Ghani, Markussen et al. and Haarasilta would render the claimed invention obvious to a person of ordinary skill in the art.

### ***Double Patenting***

16. Claims 18-23, 31-35, 39-40 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-16, 22 of U.S. Patent No. 6500426.

17. This rejection has been discussed at length in Paper No. 30, mailed on 2/24/2003.

18. Applicants submit that the present application and that of U.S. Patent No. 6500426 were filed on the same day and both claim priority to U.S. provisional application No. 60/048,611 and EPO application No. 97201641.4. Therefore, U.S. Patent No. 6500426 is not properly cited reference against the present application.

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19. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the double patenting rejection previously applied. While the Examiner acknowledges that the instant application and that of U.S. Patent No. 6500426 were filed on the same day and both claim priority to U.S. provisional application No. 60/048,611 and EPO application No. 97201641.4, it is noted that the filing dates of the instant application and that of U.S. Patent No. 6500426 are not relevant to the double patenting analysis for the following reasons. Both applications have the same filing date, there is no evidence of administrative delay on the part of the Office causing delay in prosecution of the instant application, and there is no evidence of record that the claims could not have been filed in the same application as that of U.S. Patent No. 6500426. In addition, it does not appear that the instant application was filed as a result of a restriction requirement. Therefore, for the reasons of record and those set forth above, this rejection is maintained.

#### *Conclusion*

20. No claim is in condition for allowance.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

22. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the

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notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
October 22, 2003

*Delia M. Ramirez*  
RENEGAZ, PH.D.  
PATENT EXAMINER  
10/22/03  
1652